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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.09.2001
C(2001) 2734

NOT FOR PUBLICATION

COMMISSION DECISION

of 20.09.2001

amending Decision C(1999) 939 on the marketing authorisation for the medicinal product for human use

"CETROTIDE - Cetrorelix (as acetate)"

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC

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of 20.09.2001

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"CETROTIDE - Cetrorelix (as acetate)"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1] as amended by Commission Regulation (EC) No 649/98,[2]

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93,[3] as amended by Commission Regulation (EC) No 1069/98,[4] and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "CETROTIDE - Cetrorelix (as acetate)" entered in the Community register of medicinal products under No(s) EU/1/99/100/001-003 authorised by Commission Decision C(1999) 939 of 13 April 1999, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Ares-Serono (Europe) Ltd submitted an application on 26 January 2001 pursuant to Article 6(1) of Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered the favourable opinion formulated on 31 May 2001 by the Committee for Proprietary Medicinal Products.

(4) Decision C(1999) 939 should therefore be amended accordingly.

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[1] OJ L 214, 24.8.1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 55, 11.3.1995, p. 15.
[4] OJ L 153, 27.5.1998, p. 11.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(1999) 939 is amended as follows:

1. Annex I is replaced by Annex I to this Decision;

2. Annex III (B) is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to Ares-Serono (Europe) Ltd, 24 Gilbert Street, London W1Y 1RJ, United Kingdom.

Done at Brussels, 20.09.2001.

For the Commission
Erkki LIIKANEN
Member of the Commission